

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (ORIGINAL) A method for detecting prostate cancer in a subject comprising measuring kallikrein 11 and prostate specific antigen (PSA) in a sample from the subject.
2. (CURRENTLY AMENDED) A method as claimed in claim 1 for detecting prostate cancer in a subject comprising:
 - (a) determining the amount of kallikrein 11 in a sample from the subject;
 - (b) determining the amount of PSA in the sample;
 - (c) mathematically combining the results of step (a) and step (b); and
 - (d) relating the combination to the presence of prostate cancer.
3. (CURRENTLY AMENDED) A method as claimed in claim [[1or]] 2 wherein in step (a) kallikrein 11 is determined using antibodies that specifically bind to kallikrein or a part thereof.
4. (CURRENTLY AMENDED) A method as claimed in claim [[1,]] 2, [[or 3]] wherein in step (b) the PSA is measured using antibodies that specifically bind to PSA or a part thereof.
5. (ORIGINAL) A method as claimed in claim 2 wherein in step (a) kallikrein 11 is determined in the sample by
 - (a) incubating a sample from the subject with a first antibody that specifically binds kallikrein 11 which is directly or indirectly labeled with a detectable substance, and a second antibody that specifically binds kallikrein 11 which is immobilized; and
 - (b) detecting the detectable substance thereby determining kallikrein 11 in the sample.
6. (CURRENTLY AMENDED) A method as claimed in claim 2, ~~3, 4, or 5~~ wherein in step (b) total PSA is determined in the sample.

7. (CURRENTLY AMENDED) A method as claimed in ~~any of claims 2 to 6~~ claim 2 wherein the combination is a ratio of kallikrein 11 to total PSA, or the inverse thereof.
8. (CURRENTLY AMENDED) A method as claimed in ~~any preceding~~ claim 2 which further comprises the step of determining the % free PSA and relating the combination and % free PSA to the presence of prostate cancer.
9. (CURRENTLY AMENDED) A method as claimed in ~~any preceding~~ claim 2 wherein the combination is compared to a predetermined standard.
10. (ORIGINAL) A method for distinguishing prostate cancer from benign prostatic hyperplasia (BPH) in a subject comprising determining the amount of kallikrein 11 contained in a sample from the subject, and relating the amount to the presence of prostate cancer or BPH in the subject.
11. (ORIGINAL) A method as claimed in claim 10 wherein the kallikrein 11 is measured using antibodies that specifically bind to kallikrein 11 or a part thereof.
12. (CURRENTLY AMENDED) A method as claimed in claim 10 ~~[[or 11]]~~ wherein the amount of kallikrein 11 in the sample is compared to an amount determined for a standard.
13. (ORIGINAL) A method as claimed in claim 12 wherein the standard is an amount of kallikrein 11 associated with prostate cancer.
14. (ORIGINAL) A method as claimed in claim 13 wherein an amount of kallikrein 11 in the sample greater than the standard is indicative of BPH.
15. (ORIGINAL) A method as claimed in claim 12 wherein the standard is an amount of kallikrein 11 associated with BPH.

16. (ORIGINAL) A method as claimed in claim 15 wherein an amount of kallikrein 11 in the sample lower than the standard is indicative of prostate cancer.
17. (CURRENTLY AMENDED) ~~[[A]]~~ The method for distinguishing prostate cancer from benign prostatic hyperplasia (BPH) ~~in a subject according to claim 10,~~ comprising:
- (a) determining the amount of kallikrein 11 contained in a sample from the subject;
 - (b) determining the amount of total PSA contained in the sample;
 - (c) mathematically combining the results of (a) and (b);
 - (d) relating the combination to the presence of BPH or prostate cancer.
18. (ORIGINAL) A method as claimed in claim 17 wherein the combination is a ratio of kallikrein 11 to total PSA, or the inverse thereof.
19. (CURRENTLY AMENDED) A method as claimed in claim 17 ~~[[or 18]]~~ wherein the kallikrein 11 is measured using antibodies specifically reactive with kallikrein 11 or a part thereof.
20. (CURRENTLY AMENDED) A method as claimed in claim 17, ~~18 or 19~~ wherein the PSA is measured using antibodies specifically reactive with PSA or a part thereof.
21. (CURRENTLY AMENDED) A method as claimed in ~~any one of claims 17 to 20~~ claim 17 wherein the combination is compared to a combination for a standard.
22. (ORIGINAL) A method as claimed in claim 21 wherein the standard is a combination associated with prostate cancer.
23. (ORIGINAL) A method as claimed in claim 22 wherein a combination in the sample is greater than the standard is indicative of BPH.
24. (ORIGINAL) A method as claimed in claim 21 wherein the standard is a combination associated with BPH.

25. (ORIGINAL) A method as claimed in claim 24 wherein a combination in the sample lower than the standard is indicative of prostate cancer.
26. (CURRENTLY AMENDED) A method of ~~any one of claims 17 to 25~~ claim 17 further comprising determining the percentage of free PSA and correlating the percentage free PSA and the combination to the presence of prostate cancer or BPH in the subject.
27. (ORIGINAL) A method for determining the presence of BPH or prostate cancer in a subject comprising:
- (a) providing a first binding agent that specifically binds to kallikrein 11;
 - (b) providing a second binding agent that specifically binds to PSA;
 - (c) contacting the first agent and second agent with the sample under a condition that allows the formation of a first complex comprising the first agent and the kallikrein 11, and a second complex comprising the second agent and the PSA;
 - (d) determining the presence or amount of the first and second complexes;
 - (e) mathematically combining the amount of the first and second complexes; and
 - (f) relating the combination to the presence of BPH or prostate cancer.
28. (ORIGINAL) A method as claimed in claim 27 wherein the combination is a ratio of the first complex to the second complex, or the inverse thereof.
29. (CURRENTLY AMENDED) A method of claim 27 [[or 28]] wherein the binding agents are antibodies.
30. (CURRENTLY AMENDED) A method of claim 27 [[or 28]] further comprising determining the percentage of free PSA and correlating the percentage free PSA and the combination to the presence of prostate cancer or BPH in the subject.
31. (CURRENTLY AMENDED) A method of ~~any preceding~~ claim 6 wherein the subject has total PSA between about 4-10 ng/ml.

32. (CURRENTLY AMENDED) A method of ~~any preceding~~ claim 6 wherein the subject has total PSA less than 4 ng/ml.
33. (CURRENTLY AMENDED) A method of ~~any preceding~~ claim 2 wherein the sample is a mammalian tissue sample.
34. (CURRENTLY AMENDED) A method of ~~any preceding~~ claim 2 wherein the sample is a sample of human physiological fluid.
35. (CURRENTLY AMENDED) A method of ~~any preceding~~ claim 2 wherein the sample is serum, seminal plasma, urine, or plasma.
36. (CURRENTLY AMENDED) A method of improving the accuracy of a diagnosis of prostate cancer comprising the steps of: a) performing a method of ~~any of the preceding~~ ~~claims~~ claim 2; and b) performing at least one of a test for free PSA and a digital rectal examination.
37. (CURRENTLY AMENDED) A method of claim 1 or screening for detecting prostate cancer in a subject by determining the ratio between the measured kallikrein 11:total PSA in a subject's serum sample of the subject.
38. (CURRENTLY AMENDED) A method for ~~differentiation between~~ distinguishing prostate cancer from BPH in accordance with claim 17 wherein the sample is a serum sample and wherein step (c) comprises ~~or prostate cancer by~~ determining the ratio between kallikrein 11:total PSA in a ~~subject's~~ serum sample of the subject.
39. (CANCELED)
40. (ORIGINAL) A kit for determining the presence of BPH or prostate cancer in a subject, comprising:
(a) a known amount of a first binding agent that specifically binds to kallikrein 11; and

- (b) a known amount of a second binding agent that specifically binds to PSA;
wherein the first and second binding agents comprise a detectable substance, or bind directly or indirectly to a detectable label.

41-49. (CANCELED)

50. (NEW) A method of claim 10 wherein the subject has total PSA between about 4-10 ng/ml.

51. (NEW) A method of claim 10 wherein the subject has total PSA less than 4 ng/ml.

52. (NEW) A method of claim 10 wherein the sample is a mammalian tissue sample.

53. (NEW) A method of claim 10 wherein the sample is a sample of human physiological fluid.

54. (NEW) A method of claim 10 wherein the sample is serum, seminal plasma, urine, or plasma.